Effectiveness and cost-effectiveness of a virtual Community of Practice in the empowerment of patients with ischemic heart disease: An ongoing randomized controlled trial (e-MPODERA2 project)

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BACKGROUND

Virtual Communities of Practice (VCoP) offer access to information and exchange possibilities for people in similar situations, which might be especially valuable for the **self-management of chronic diseases**.

There is scarce evidence on the clinical impact of these interventions on people with chronic conditions.

METHOD

A **pragmatic randomised controlled trial** is being performed in Catalonia, Madrid and Canary Islands, Spain.

Three-hundred patients with a recent diagnosis of ischemic heart disease (IHD) attending GP practices and hospitals should be selected and randomised to the intervention or control group to reach an adequate sample size.

The intervention group is being offered participation for 12 months in a VCoP based on a gamified web 2.0 platform with educational material, as well as interaction with other patients and a multidisciplinary professional team. Intervention and control groups are receiving usual care.

- **Primary outcome**: measured with the Patient Activation Measure (**PAM**) questionnaire at baseline, 6, 12 and 18 months.
- **Secondary outcomes** include: clinical variables; self-efficacy on managing the disease (**Self-management of Chronic Disease Scale, SMCDS**), quality of life (**EuroQoL questionnaire, EQ-5D-5L**), self-perceived general health (**EQ-VAS**), anxiety and depression (**Hospital Anxiety and Depression Scale, HADS-A & HADS-D**). Data is collected from self-reported questionnaires and electronic medical records.

Table 1. Characteristics of patients

	Intervention group (n = 108)	Control group (n = 101)
Age, M (SD)	58.34 (8.68)	59.47 (9.34)
Gender, n (%)		
Women	21 (19.4)	15 (14.9)
Men	84 (77.8)	84 (83.2)
Autonomous Community, n (%)		
Canary Islands	24 (22.2)	33 (32.7)
Catalonia	51 (47.2)	33 (32.7)
Madrid	33 (30.6)	35 (34.7)
Marital status, n (%)		
Single	10 (9.3)	7 (6.9)
Married	69 (63.9)	65 (64.4)
With partner	11 (10.2)	7 (6.9)
Separated/divorced	14 (13.0)	10 (9.9)
Widow	2 (1.9)	3 (3)
Living alone, n (%)	13 (12.0)	10 (9.9)
Educational level, n (%)		
Primary education not completed	1 (0.9)	5 (5)
Primary education	21 (19.4)	18 (17.8)
Secondary education	37 (34.3)	33 (32.7)
Tertiary education	46 (42.6)	41 (40.6)
Clinical variables	**Intervention group (n = 98)**	**Control group (n = 87)**
Obesity, n (%)	19 (19.4)	23 (26.4)
If obese, body mass index, M (SD)	31.4 (1.5)	32.9 (3.1)
Smoker, n (%)	37 (37.8)	32 (36.8)
Lipid profile		
HDL-C, M (SD)	43.5 (12.7)	44.5 (25.0)
LDL-C, M (SD)	95.7 (41.8)	92.9 (37.3)
Number of angina episodes in the last week, M (SD)	0.2 (0.8)	0.3 (0.6)
Duration of the ischemic heart disease, in months, M (SD)	9.1 (6.7)	9.6 (8.3)

RESULTS

- Two hundred and nine participants have been recruited so far. Intervention and control groups did not show significant differences at baseline in any variable (**Tables 1 and 2**).
- At the time of the analysis, 142 participants have completed 6 months since recruitment, showing a rate of missing values between 19.0%-20.4% depending on the questionnaire (**Table 3**).
- Among completers, the intervention did not show significant effects on any of the assessed measures (**Table 3**). A tendency towards significance was found for self-efficacy on managing the disease: the intervention group obtained a better result than the control group.

Table 2. Baseline scores of dependent variables

	INTERVENTION	CONTROL	p*
PAM (0-100) (n=169)	61.7 (15.9)	62.8 (14.7)	0.648
SMCDS (4-40) (n=172)	26.4 (8.0)	27.5 (7.7)	0.359
EQ-5D-5L (0-1) (n=171)	0.87 (0.14)	0.86 (0.16)	0.976
EQ-VAS (0-100) (n=172)	75.7 (19.3)	71.5 (23.5)	0.198
HADS-A (4-28) (n=169)	12.7 (3.7)	13.1 (4.5)	0.543
HADS-D (4-28) (n=170)	10.6 (3.5)	11.2 (4.3)	0.324

*p-value from Student's t-test for independent samples

Table 3. Effect of the intervention at 6-month follow-up in study completers

N = 110-115	CONTROL	INTERVENTION	B (p)*
PAM (0-100)	60.5 (15.7)	63.9 (15.5)	3.8 (0.149)
SMCDS (4-40)	27.3 (8.9)	27.9 (8.3)	1.9 (0.088)
EQ-5D-5L (0-1)	0.86 (0.15)	0.90 (0.13)	0.0 (0.383)
EQ-VAS (0-100)	73.6 (24.7)	79.9 (16.3)	5.2 (0.152)
HADS-A (7-28)	12.7 (4.0)	12.2 (3.9)	-0.4 (0.482)
HADS-D (7-28)	10.9 (4.2)	10.2 (3.6)	-0.4 (0.458)

*Unstandardized coefficients (p-value) from linear regression models with group allocation as independent variable, adjusting for the baseline value of the dependent variable

CONCLUSIONS

- Due to the COVID-19 situation, which is affecting primary and specialized care, recruitment is a major challenge. Participants will continue to be recruited continuously until the desired sample size is achieved in order to maintain the integrity and validity of the trial.
- The results of this study will provide evidence on the effectiveness and cost-effectiveness of an alternative way of managing patients with a recent diagnosis of IHD by using a VCoP, which could be extended to other chronic patients/settings.

POINTS FOR DISCUSSION

- How to optimize patient recruitment with the COVID-19 situation.
- Usefulness of VCoP for IHD and other chronic diseases: strengths and limitations.
- How to overcome the barriers and limitations that VCoP might pose for people with chronic diseases.